

**BECKMAN**

K964762

**Summary of Safety & Effectiveness**  
**IMAGE™ Immunochemistry System Ceruloplasmin (CER) Reagent**

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**1.0 Submitted By:**

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**2.0 Date Submitted:**

26 November 1996

**3.0 Device Name(s):**

**3.1 Proprietary Names**

IMAGE™ Immunochemistry System Ceruloplasmin (CER) Reagent

**3.2 Classification Name**

Ceruloplasmin immunological test system (21 CFR § 866.5210)

**4.0 Predicate Device(s):**

IMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMAGE System Ceruloplasmin (CER)	Beckman Ceruloplasmin (CER)	Beckman Instruments, Inc.	K791339

**5.0 Description:**

The IMAGE Immunochemistry System CER Reagent in conjunction with Beckman Calibrator 2, is intended for use in the quantitative determination of ceruloplasmin concentrations in human serum samples on Beckman's IMAGE Immunochemistry System.

**Beckman Instruments, Inc.**

#### 6.0 Intended Use:

The IMMAGE Immunochemistry System Ceruloplasmin (CER) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human ceruloplasmin by rate nephelometry.

#### 7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System CER Reagent	Analytic Range	Same as Beckman Ceruloplasmin reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System CER Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for CER.
	Antibody concentration	IMMAGE CER has a higher antibody concentration than the Beckman Ceruloplasmin reagent

#### 8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Beckman Reagent on the Array® 360 System to the IMMAGE System Reagent.

**Method Comparison Study Results**  
IMMAGE Ceruloplasmin (CER) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE CER Reagent	serum	0.996	-2.43	0.995	104	Beckman Array Systems CER Reagent

### Stability Study Results

Reagent	Product Claim
IMAGE CER	24 month shelf-life 14 day open container stability 14 day calibration stability

### Estimated Imprecision

TYPE OF PRECISION	SAMPLE	Data Points	Test Mean Value (mg/dL)	SD (mg/dL)	% CV
Within Run	Serum Level 1	80	13.6	0.42	3.1
	Serum Level 2	80	49.3	1.20	2.4
	Serum Level 3	80	88.0	2.72	3.1
Total	Serum Level 1	80	13.6	0.52	3.8
	Serum Level 2	80	49.3	1.74	3.5
	Serum Level 3	80	88.0	3.76	4.3

TYPE OF PRECISION	SAMPLE	Data Points	Test Mean Value (mg/dL)	SD (mg/dL)	% CV
Within Run	Low Serum Level 1	30	1.4	0.08	5.8
	Low Serum Level 2	30	4.3	0.17	3.9
Total	Low Serum Level 1	30	1.4	0.09	6.6
	Low Serum Level 2	30	4.3	0.17	3.9

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.